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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,309	04/16/2004	Richard S. Kusleika	12013/48803	7747
23838	7590	10/16/2007		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER VU, QUYNH-NHU HOANG	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,309

Applicant(s)

KUSLEIKA, RICHARD S.

Examiner

Quynh-Nhu H. Vu

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/16/04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, Species A (claims 16-24) in the reply filed on 10/04/07 is acknowledged.

Claims 1-15 and 25-30 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "radially expanding a tissue dilatation means" is vague and unclear. Does applicant mean "a balloon 24" or "a tissue of treatment"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 16-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Machold et al. (US 5,611,775).

Machold discloses a method of using the catheter for the delivery drugs for treating tissue into body lumen comprising: intraluminally advancing an elongate flexible catheter 10, 13 until a flexible treatment sheath 19 mounted to a distal end region of the catheter is adjacent a predetermined treatment site; and supplying a treatment fluid under pressure to a compartment formed by the treatment sheath (through lumen 14) to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site (see Figs. 1-5), cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact (see col. 2, line 32-col. 4, line 32 or claims 1-13).

Regarding claims 17-18 and 22-23, while maintaining the sheath in said intimate and substantially conforming contact, radially expanding a dilatation means 16 within the compartment until the dilatation means engages the treatment sheath, then further radially expanding the dilatation means whereby the dilatation means acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue; following said dilatation, radially contracting the dilatation means while maintaining the treatment sheath in said contact-to administer the treatment fluid to the dilated tissue; and following said administering of the treatment fluid, discontinuing the supplying of the treatment fluid to allow the treatment sheath to radially contract under a residual elastic force; wherein the dilatation means comprises a dilatation balloon formed of inelastic material and radially enlargeable by supplying a dilatation fluid to a dilatation chamber; and wherein the contraction of the dilatation means comprises withdrawing the dilation fluid from the dilatation chamber to substantially evacuate the dilatation balloon (see col. 2, line 32-col. 4, line 32 or claims 1-13).

Regarding claim 19, the method inherently includes that positioning a guide wire 22 with a distal end thereof outside of the body, inserting the proximal end of the guide wire within the distal end of a guide wire running through the catheter, and advancing the catheter distally relative to the guide wire.

Regarding claim 20, supplying of the treatment fluid includes comprising the treatment fluid to the compartment of balloon 19 via treatment fluid supply lumen (through the lumen 14) of the catheter at a predetermined treatment fluid pressure.

Regarding claim 21, the supplying of the treatment fluid-comprises causing the treatment fluid to perfuse through multiple pores 20 in the treatment sheath.

Regarding claim 24, while maintaining the treatment sheath in substantially conforming contact, allowing a flow of body fluids through the catheter past the treatment site (see Figs. 4-5).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Quynh-Nhu H. Vu
Examiner
Art Unit 3763



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